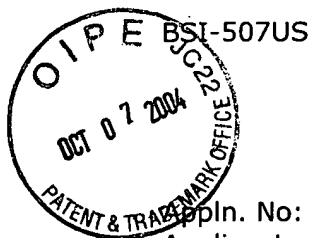


AF/3738
EJW

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/082,920
Applicant: Leonard Pinchuk
Filed: February 25, 2002
Title: A Method of Treating An Aneurysm
T.C./A.U.: 3738
Examiner: Paul B. Prebilic
Confirmation No.: 3520
Notice of Appeal Filed: May 14, 2004
Docket No.: BSI-507US

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

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S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated January 8, 2004, and the Advisory Action dated May 3, 2004, of claims 1-6.

This Brief is presented in the format required by 37 C.F.R. § 1.192, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 1.192(a), this Brief is being filed in triplicate within the time allowed for response to the Notification of Non-Compliance with 37 C.F.R. § 1.192(c).

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Scimed Life Systems of One Scimed Place; Maple Grove, Minnesota by virtue of an assignment recorded on May 8, 2003, at Reel/Frame 013006/0656.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1-6 stand rejected under 35 U.S.C. § 112 ¶1, as failing to comply with the written description requirement. Specifically, the Examiner rejects claim 1, steps (c) and (d) as not inherently described in the application. In particular, the Examiner asserts that there is no original support for: (1) making the restriction means with a restricted diameter greater than the vessel diameter; and (2) trimming the length to a length greater than the aneurysm when the stent is expanded to that maximum diameter.

Claims 1-6 are presented below.

1. A method of treating an aneurysm with a stent-graft comprising the steps of:
 - (a) determining the length of the aneurysm;
 - (b) determining the diameter of the vessel into which a stent-graft will be placed;
 - (c) providing a stent-graft having dilation restriction means for restricting dilation of said stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter of step (b);
 - (d) trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter.
2. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a suture material.
3. The method of claim 2 wherein said suture material is flexible and substantially inelastic.
4. The method of claim 1 wherein said stent-graft is made of woven wires and a suture material is woven through said wires.

5. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a plurality of sutures spaced along said stent-graft.
6. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a plurality of sutures located in a plurality of substantially parallel planes which are substantially perpendicular to a longitudinal axis of said stent-graft.

IV. STATUS OF AMENDMENTS

Applicant's proposed amendments to the specification in the Response dated April 7, 2004, are indicated as entered as of the date of the Advisory Action. No claim amendments are pending.

V. SUMMARY OF INVENTION

The present invention, unlike anything taught or suggested in any known prior art, is directed to a method of preventing dislodgment of a stent that has been implanted in a vessel for a long period of time. This problem is shown by example in prior art Figures 8-11. To overcome this problem, the claimed invention recites a method of providing a stent-graft having a dilation restriction means (see page 10, lines 1-8) for restricting dilation of the stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter into which the stent-graft will be deployed (see page 9, lines 23-28), and then trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter (see page 9, lines 29-44). The claimed invention is also illustrated by specific embodiments shown in Figures 13-15. This claimed method insures that the stent-graft will not later shorten to a length less than the length of the aneurysm in the vessel and thereby dislodge.

VI. ISSUE

To determine whether applicant's steps (c) and (d) of claim 1 are adequately described in the specification, the Board should consider whether the Examiner applied the correct standard when challenging the presumed adequate written description of applicant's application, that is, has the Examiner overcome the

initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the applicant's disclosure a description of the invention defined by steps (c) and (d) of claim 1.

VII. GROUPING OF CLAIMS

Claims 1-6 stand together.

VIII. ARGUMENT

The following argument sets forth the applicable standard to determine whether claim limitations are adequately described in the written description. Then, this argument demonstrates that the Examiner has applied an incorrect standard and further failed to provide, by a preponderance of the evidence, why one of ordinary skill in the art would not recognize in the applicant's disclosure a description of the invention as defined in the claims. Finally, this argument supports the fact that even if the Examiner were to apply the correct standard and present proper evidence, the applicant has shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description adequately requires the limitations of steps (c) and (d) of claim 1.

A. A claim limitation is adequately disclosed in the written description when a person skilled in the art would recognize in an applicant's disclosure a description of the invention as defined in the claims.

It is presumed that the written description as filed is adequate unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner must have a reasonable basis to challenge the adequacy of applicant's written description. The Examiner's challenge is conducted from the standpoint of one of skill in the art at the time the application was filed. *See, e.g., Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993). From this standpoint, the Examiner determines the field of the invention and the level of

one of ordinary skill in the art at the time the application was filed. If the Examiner contends that claims are not supported, the Examiner should clearly establish the claim limitation at issue. Then, the Examiner must present a *prima facie* case why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. See MPEP 2163(III)(A).

Generally, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). There is no *in haec verba* requirement in order to satisfy the written description requirement and newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. See MPEP 2163(I)(B). If an applicant discloses in a patent application a device that inherently performs a function, has a property, operates according to a theory, or has an advantage, the patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. If the adequacy of an inherent written description is challenged by an Examiner, the applicant may show inherency by establishing that even though the explicit limitation in a claim "is not present in the written description whose benefit is sought . . . a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

B. The Examiner has not overcome the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in applicant's disclosure a description of steps (c) and (d) of claim 1.

First, the Examiner has applied the wrong standard in determining that applicant's steps (c) and (d) are not disclosed in applicant's written description. As enunciated above, when an applicant is relying on inherent disclosure, the standard is whether a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation. In contrast, in the January 8, 2004 Final Office Action, the Examiner's rejection of claim 1, steps (c) and

(d), was based on the standard that they "would lack clear antecedent basis from the written description." (Emphasis Added). Furthermore, in the subsequent Advisory Action dated May 3, 2004, the Examiner re-asserted the Section 112 rejection through application of the same incorrect standard, although worded somewhat differently. The Examiner stated, "In particular, . . . there is no original support for making the restricted means with a restricted diameter greater than the vessel diameter and also trimming the length to a length greater than the aneurysm when the stent is expanded to that maximum diameter." (Emphasis Added). The applicant submits that the standard to determine adequacy of the written description for an inherent claim limitation is not "lacking clear antecedent basis" or "no original support," but whether a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation. Thus, the Examiner has clearly applied the wrong standard.

Moreover, the Examiner stated in the Final Office Action, "Even if it can be shown to be inherent based upon the figures, it [steps (c) and (d) of claim 1] still would lack clear antecedent basis from the written description." This is contrary to established law because drawings alone may provide a written description of the invention as required by Section 112. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 62 USPQ2d 1846 (Fed. Cir. 2002); *see also, Mendenhall v. Cedarapids, Inc.*, 28 USPQ2d 1081 (Fed. Cir. 1993) (in those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification).

Second, the Examiner has not overcome the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in applicant's disclosure a description of the invention defined by the claims. In fact, the Examiner fails to provide any evidence to support the Section 112 rejection. In the Final Office Action, with respect to steps (c) and (d) of claim 1, the Examiner simply states that the limitations in question lack original support in that there is no clear disclosure of the limitations in the original specification. Similarly, in the Advisory Action, the Examiner concludes steps (c) and (d) are not inherently described, but then again fails to provide any evidentiary support for that conclusion. The Examiner again states, "there is no original support for making the restricted means with a restricted diameter greater than the vessel diameter and also

trimming the length to a length greater than the aneurysm when the stent is expanded to that maximum diameter.” The Examiner fails to provide any evidence relating to why one skilled in the art would not recognize applicant’s claim limitations as described in the specification to support the rejection. Because the Examiner failed to provide any supporting evidence, let alone, a *preponderance of evidence*, the Examiner has clearly failed to show why a person skilled in the art would not recognize in applicant’s disclosure a description of the invention as claimed in steps (c) and (d) of claim 1. The applicant submits that the Examiner has therefore failed to overcome the initial burden that applicant’s written description is presumed adequate.

C. Applicant asserts that steps (c) and (d) of claim 1 are described because applicant has shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.

The specification of the patent application teaches to one skilled in the art steps (c) and (d) of claim 1. The method of step (c) requires “providing a stent-graft having dilation restriction means for restricting dilation of said stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter of step (b).” Step (c) has two requirements: 1) that the stent-graft has a dilation restricting means to prevent the stent-graft from dilating past a specific diameter, and 2) that specific diameter is greater than the diameter of the vessel into which the stent-graft is deployed.

In the Summary of the Invention at page 4, lines 11-14, the specification states that it is an object of the invention to provide an endoluminal stent-graft which is resistant to dilation. Further it is an object of the invention to provide an endoluminal stent-graft which is restricted from dilation beyond a selected point. Thus, the first requirement of step (c) would be clearly identified by one skilled in the art from reading the specification.

The second requirement of step (c) would also be identified by one skilled in the art. At page 5, lines 23-33, the specification describes the process by which a physician would determine the resulting length of a stent-graft after dilation due to the shortening of the length of the stent-graft which occurs during dilation.

As understood by one of ordinary skill in the art reading the specification, the length of a stent-graft decreases as its diameter increases. Over time, a stent-graft continues to dilate and thereby continues to shorten as depicted in FIGS. 9-10. At lines 27 and 30 of page 7, the specification states, "the doctor would correlate the maximum allowable diameter of the stent with the minimum length of that particular stent needed to bridge the aneurysm." In this manner, the doctor would define a minimum length for the stent-graft that would still prevent the stent-graft from dislodging from the aneurysm as shown in FIG. 11. Therefore, the second requirement of step (c) would also be understood by one skilled in the art reading the specification.

Regarding step (d), the specification provides unambiguous support. At page 7, lines 31-33, it is stated, "That suitable sized and appropriately restricted stent-graft [as determined in step (c)] is then cut to length and deployed in the aneurysm." Although step (d) uses the term "trimming the stent-graft to a length [as determined in step (c)]," the applicant asserts that one skilled in the art would have understood the step of trimming by reading the specification which teaches sizing the stent-graft by cutting it to length.

Even if, for argument sake, the Examiner applied the correct standard and presented, by a preponderance of the evidence, facts sufficient to challenge the presumption of adequacy of applicant's written description as described in detail above, applicant submits that steps (c) and (d) of claim 1 are nonetheless described because applicant has responded to the Examiner's challenge and shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires those limitations.

In applicant's reply to the Office Action of January 8, 2004, applicant argued as to claim 1, step (c), that one of ordinary skill in the art would understand that it is impossible to deploy a stent-graft into a vessel to repair an aneurysm if the maximum possible diameter of the stent-graft is less than the vessel diameter. Not only would the stent-graft not stay in place, blood would flow around the outside of the graft and into the aneurysm. If the stent did not expand to a diameter greater than the diameter of the vessel, the stent would not work for its intended purpose. That is, the very thing sought to be prevented in bridging the aneurysm with the

stent-graft, would occur. This limitation on the maximum diameter of the stent-graft present in step (c) would clearly be known to one skilled in the art reading the disclosure of the present invention.

With regard to claim 1, step (d), which covers the trimming of the stent graft to a particular length prior to deployment, applicant argued this aspect of the trimming step would be clearly known to one skilled in the art reading the invention disclosure. Indeed, if the stent-graft were trimmed to a length *less* than the length of the aneurysm when the stent-graft is dilated to its maximum diameter, the stent-graft would shorten to a length *less* than the length of the aneurysm at full radial dilation and become dislodged. Again, the entire purpose of the invention would be lost, that is, as described throughout the specification and prosecution, to restrict the maximum diameter (radial dilation) to a point that **prevents** shortening of the stent beyond a catastrophic point and subsequent dislodgement. Therefore, this limitation on the trimming step would also clearly be known to one skilled in the art reading the disclosure of the present invention.

Applicant successfully convinced the Examiner of the adequacy of support for step (b) (not discussed herein), but was unable to convince the Examiner that steps (c) and (d) were similarly supported. The Examiner, however, did not provide sufficient rebuttal evidence (as discussed in Section B, *supra*) and maintained the rejection. Therefore, the applicant respectfully asserts that the Examiner is in error.

D. Conclusion

The Examiner has applied an incorrect standard in determining the adequacy of applicant's written description. The Examiner challenged the adequacy of applicant's written description and the applicant responded by showing why one of ordinary skill in the art would recognize the claim limitations from applicant's disclosure. The Examiner failed to respond to applicant's showing by presenting a preponderance of evidence, why a person skilled in the art would not recognize, in applicant's disclosure, a description of the invention as defined by steps (c) and (d) of claim 1. The applicant has made clear that the descriptive matter of step (c), providing a stent-graft having dilation restriction means for restricting dilation of said

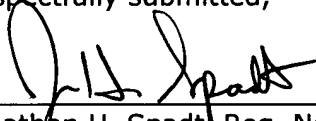
stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter, and step (d), trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter, is supported in the specification and moreover, would be recognized by one of ordinary skill in the art to be part of applicant's disclosure.

The applicant respectfully submits that in view of the above, claims 1-6 are in a condition for allowance and requests that the Board reverse the Examiner's rejection.

IX. APPENDIX

An appendix containing a copy of the claims involved in the appeal is attached.

Respectfully submitted,



Jonathan H. Spadt, Reg. No. 45,122
Christian M. Bauer, Reg. No. 51,443
Attorneys for Applicant

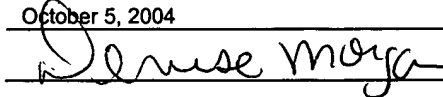
Dated: October 5, 2004

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

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IX. APPENDIX

1. A method of treating an aneurysm with a stent-graft comprising the steps of:
 - (a) determining the length of the aneurysm;
 - (b) determining the diameter of the vessel into which a stent-graft will be placed;
 - (c) providing a stent-graft having dilation restriction means for restricting dilation of said stent-graft beyond a maximum diameter which maximum diameter is greater than the vessel diameter of step (b);
 - (d) trimming the stent-graft to a length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter.
2. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a suture material.
3. The method of claim 2 wherein said suture material is flexible and substantially inelastic.
4. The method of claim 1 wherein said stent-graft is made of woven wires and a suture material is woven through said wires.
5. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a plurality of sutures spaced along said stent-graft.
6. The method of claim 1 wherein the dilation restriction means of the stent-graft provided in step (c) is comprised of a plurality of sutures located in a plurality of substantially parallel planes which are substantially perpendicular to a longitudinal axis of said stent-graft.